# VISI Conference Call

## 2001-May-16 11:00 am EDT

## Agenda and Minutes

**Participants:**

| | | |
|---|---|---|
| ✓ | Calabrese, Tom | GlaxoSmithKline (GSK) |
| ✓ | Del Nicki, Ray | Uniform Code Council (UCC) |
| ✓ | Fan, Sarah X. | Wyeth Lederle Vaccines (WAL) |
| ✓ | Filipski, Ron | PFP Consultants |
| ✓ | Gallagher, Maryann R. | FDA |
| ✓ | Gilbert, Jayne | Chiron (CHIR) |
| ✓ | Heijbel, Harald | Swedish Inst. of Infectious Disease Control |
| ✓ | Ippolito, Carol | CDC (NIP/TRW) |
| ✓ | Kim Joann | American Academy of Pediatrics (AAP) |
| ✓ | Maher, Katie | Merck & Co. (MRK) |
| ✓ | Maher, Lugene | Wyeth Lederle Vaccines (WAL) |
| ✓ | Mundt, James | Merck & Co. (MRK) |
| ✓ | Purvis, William | FDA (CBER) |
| ✓ | Roberts, John | Uniform Code Council (UCC) |
| ✓ | Snyder, Bob | CDC (NIP) |
| ✓ | Varricchio, Frederick | FDA (CBER) |
| ✓ | Walop, Wikke | Health Canada |
| ✓ | Weniger, Bruce | CDC (NIP) |

### 1. Introductions

- Bill Purvis of the FDA announced that he will be retiring soon (after 35 years of service) and that Maryann Gallagher will replace him as agency liaison with VISI.

### 2. VISI guidelines editing and website reformatting (Bruce Weniger)

#### 2.a Replacement of previous contract editor in early May; introduction of Carol Ippolito

- The new contract editor to work on editing the VISI documentation, Carol Ippolito, was introduced. She provided a summary of her previous work and said she would record the attendance and take notes of the conference call.

#### 2.b Loss of website contract webmaster; replacement not yet identified and assigned

- Bruce Weniger reported that a second contract webmaster who recently started work on the VISI would be replaced in the next weeks, but the replacement had not yet been identified. This person's tasks will include formatting the website, creating a public comment feedback page for it, tweaking and updating the NDC database, and other web-related tasks.

- He said it was likely the formal draft of the VISI guidelines to be announced for public comment, as well as its final documentation, would consist of a single file in Adobe® Acrobat portable document format (.pdf), which would replace the existing .htm pages at the website.

**3. RSS barcode printing developments (John Roberts)**

**3.a Recent UCC demonstration of RSS barcodes on meat products and loose produce. Press release and background at: www.uc-council.org/news/ne_050201.html**

- John Roberts clarified that the Uniform Code Council (UCC) is a non-profit standards organization, and not a vendor selling any hardware or software related to trade identification numbering or barcoding. The VISI Industry Forum minutes (see below) had listed UCC among "vendors". He said the Reduced Space Symbology (RSS™) barcode was patented by UCC, but placed in the public domain for use without royalty.
- As noted in an email he distributed on 8 May, John reported on the 100% successful testing of the RSS in Europe for groceries -- loose produce and meat. In response to a question from Jim Mundt, John said the Europeans were planning to track meat from its origin to the consumer, and that RSS barcoding would be used to embed numbers encoding its country, county, and even specific ranch or farm of origin, as well as other routine information such as its global trade identification number (GTIN), price per pound, etc.
- John also said he circulated another email on 14 May regarding the endorsement by the European food and drink industry trade association of the use of the EAN/UCC numbering system and barcoding for food products.
- He said the RSS was developed principally for the kind of small packaging common in healthcare, with the UCC responsible for the U.S. and Canada, and its partner, EAN responsible for Europe and the rest of the world. A global meeting on RSS in healthcare is scheduled for 31 May and will involve 12 countries sending representatives.
- In the Netherlands, RSS was successfully pilot tested by a pharmaceutical packaging company on single-unit-dose blister packages used in Dutch hospitals (filled with mints instead of medicine). John scanned a copy of the EAN correspodence as well as both sides of the unit-dose packages, and circulated it in his 8 May email. Bruce agreed to forward the .jpg image onwards to the entire VISI working group.
- Germany has its own EAN-affiliated organization, which on its own initiative has been working with Merck KGaA, a pharmaceutical company in Germany (www.merck.de/english/services/pharma/index.htm; not affiliated with Merck & Co. of the U.S.A.). The German Merck has also successfully tested RSS on their own products, but its "rollout" onto the market is awaiting a management decision.
- In the U.S.A., Alcon Laboratories ( www.alconlabs.com/ ), a division of Nestlé, is using RSS on their eye drops product line to embed only the GTIN (which is the NDC – National Drug Code -- in U.S. products), because the package is too small for a traditional UPC (Universal Product Code). Abbott Laboratories is using RSS on their entire product line for the linear 1-dimensional

component only, but eventually they will add the 2-dimensional component with the lot number and expiration date.

- Upon request by the Veterans Administration's consolidated mailout pharmacy service (CMOPS), Pharmacia (Upjohn) is embedding the lot number and expiration into an RSS composite (1- and 2-dimensionals) barcode, as well as the NDC in the traditional large UPC, on their large bottles of pills. They will be testing this RSS composite in June, July, and August at their Chicago, IL and Leavenworth, KA facilities.
- Jayne Gilbert asked whether the RSS barcode would require purchase of new scanners. The answer was perhaps, depending on the age of their existing equipment. Most older laser scanners, and all wands, could not read the 2-dimensional RSS component. She asked how costly were the newer devices which could. John said the retail prices were around $1,500, but Bruce said the "street" prices from discount suppliers were around $800, which is what CDC paid a year ago.
- John continued that a division of Baxter Healthcare Corporation in New Jersey was putting RSS on its products, without bothering to go through a pilot testing phase.
- A question was asked whether changing or adding the RSS barcode would require FDA regulatory permission. John said no, since the barcode itself was not a mandated part of the labeling or packaging over which FDA exercised oversight. But, of course, if other parts of the packaging are rearranged to accommodate the new barcode, then it would likely need to be reviewed by FDA. Bill Purvis of FDA commented that such changes would be OK, but he was concerned that they not affect the required prominence of the brand name and proper name. He suggested a change in the package barcoding would likely fall into a "30-day" category, in which FDA is officially notified of the change by the manufacturer. If it returns no objection or inquiry within that time period, the manufacturer is free to act.
- John continued that the UCC has about 18,000 member companies in the cosmetics field, in which there is much interest in replacing the (large) UPCs with the (smaller) RSSs, because of the small size of many of their products, such as lipstick. A test of RSS on cosmetics will take place in August. Of course, any such switch by a product sold at retail would be contingent on the retail grocery industry going along to upgrade the capabilities of or replace their existing scanners.
- John mentioned that he would be attending a meeting of the National Council for Prescription Drugs in Scottsdale, AZ, on how to encode information of up to 91 characters on health cards. One problem is the different requirements of 50 different state systems. Representing the UCC, he would be promoting RSS for this purpose.

### 3.b Online high-speed printing issues

- Jane Gilbert asked what was the size of the label. John responded that the most common RSS printing size was 6.7 mil (.0067 inches) for the "x-dimension" (thickness of the thinnest bar). She asked whether the problems of printing these barcodes rapidly had been overcome. John replied that pre-printing them was easy, but that the key issue was printing them rapidly at the time of packaging when the lot number and expiration become known. The testing done at the UCC lab and by the vendors it works with documented that label stock could be printed at 6 inches per second, which is fast enough. He has not seen the Merck KGaA production line to see how fast they are doing it.
- Tom Calabrese asked whether any companies were using 3- or 4-part removable labels. John demurred, as this field was not the UCC's area of involvement or expertise.

## 4. VISI Industry Forum meeting, 26 April 2001 (Ron Filipski)

### 4.a No support for "Vaccine Facts" sidebars

- Ron Filipski summarized the position of vaccine industry representatives who comprised this VISI subcommittee, and which were circulated in minutes from its April meeting ("CDC_VISI_Industry_Forum_4-26-2001.doc"). He began by stating that the industry was very supportive of facilitating the convenient and accurate transfer of information from the primary vaccine container, and would work toward that primary goal of VISI.
- He said there was no support by industry for the VISI proposal for "Vaccine Facts" sidebars on the vaccine carton for key usage information to be provided in a printed rectangle of standard format and layout. This is because the FDA is currently proposing a revamping of the product insert paper with highlighting at its top (http://www.fda.gov/ohrms/dockets/98fr/122200a.pdf; see p. 45, nominal p. 81125). He said it was more important to have key information in the paper product insert, which he claimed is usually retained, rather than on the carton, which is usually discarded.

### 4.b Support of NDC as global trade ID number

- He said the industry subcommittee supported the use of the U.S. NDC to identify U.S. vaccines in products and databases, but that the numbering needed to fit into a global system. The database ought to be capable of expanding to accommodate global usage and be "streamlined" to make it useful. This would involve representation from FDA, CDC, BOB [Bureau of Biologics, Canada], and other countries as a joint effort.

### 4.c Support abbreviations, but not 3-characters per antigen

- The VISI industry forum wanted to expand the use of abbreviations on packaging, but was concerned about limiting abbreviations to 3 characters. He suggested that current abbreviations continue to be used.

### 4.d No support for RSS (reduced space symbology) barcode

- He said the industry was not comfortable with the use of the RSS barcode at this time on peel-off stickers. However, it did support initially the use of detachable [sticky] labels that would contain only "human readable

information" [in alphanumeric characters] for generic vaccine type or abbreviation, lot number, and manufacturer name.

**4.e Suggests economic analysis in justifying expenditure**

- Ron said the forum believed it was important to conduct economic analyses of the costs involved in such packaging and labeling innovations, to be sure they were justified by the benefits. There would certainly be an economic impact in revising existing packaging systems.

**4.f Recommends over 3-7 year period**

- The industry favored a 3-phased approach over a 3 to 7 years:
- In phase 1, single-dose vaccine vials would be provided with a single, detachable label. Later, multiple labels could be applied to multi-dose vaccine vials. End users would have to bear the cost involved.
- In phase 2, industry would convene its own working group to meet with government and users, explore technologies, consider cost/benefits, and explore the RSS and other alternative technologies, in order to develop a fully automatic system to transfer data from vial to medical record.
- In phase 3, such a system would be fully implemented.

**4.g Next steps: form industry review groups to supply required system specifications, review NDC number and abbreviations, make recommendations**

- The next steps industry believed should be taken were summarized:
- Distribute its minutes.
- Convene an industry review group develop system specifications reflecting manufacturer requirements. The forum is scheduled to meet again on 15 June to work on this.
- Carry out economic cost analyses.

**4.h Discussion**

- Bruce Weniger asked for clarification on what was meant by "system specifications". Were they technical, engineering issues such as filling line speeds, common label sizes, printing verification requirements, etc.? The answer was yes. Ron pointed out that vaccines come in a variety of presentations, such as small and larger vials and prefilled syringes. That one needed to know the cost of barcode readers to verify printing accuracy, the cost and availability of barcoding and verification software, and how to integrate all this hardware and software together. These were aspects to be included in the specifications.
- Wikke Walop described Canada's recent meeting with industry on similar issues. She reported they said "tell us what you want us to do, and how to do it, and we will."
- Ron said it would be important for the industry working group to identify representatives from FDA and CDC to participate, and that nominees should please email him (pfpflip@earthlink.net) to join the effort.
- Bruce referred to the industry concern for limiting vaccine abbreviations to 3 characters. He stated this was an inaccurate characterization of the VISI

abbreviations, which can be of any length. The VISI abbreviations simply propose that the first three characters be reserved for the disease being prevented, and that characters in position 4 and beyond be used for further specificity, as needed or desired. Regardless of whether these additional characters are subscripted, small-fonted, or just typed without formatting, they would count as characters.

- Lugene Maher asked if FDA was ready to be involved in such an activity. Bill Purvis responded that there likely would not be an official response without having something in writing to look at. He said such issues also affect [non-vaccine] drug packaging, which involves another FDA center. So they may want to look over this material, too.
- Ron emphasized the importance of getting FDA involvement from the beginning, similar to their involvement in developing the "barrier" guidelines. The effort would benefit from their early and active involvement in specifications setting, exploring alternative technology, etc., as well as providing input from the regulatory standpoint. Bill agreed, but indicated the FDA hierarchy would need to make these decisions, but that he would certainly inform the appropriate persons (Norman Baylor) and units (packaging/labeling) in the office of vaccines of CBER. Or Maryann Gallagher might actually do this, given Bill's pending retirement.
- Bruce commented on the economic analyses that were called for, agreeing with the usefulness of doing them. Although the manufacturer's costs for packaging and labeling changes would be relatively straightforward to determine and amortize per dose of vaccine, the other side of the cost ledger would be more difficult. What is the benefit in dollar terms for maintaining public confidence in the safety of vaccination and our monitoring systems to detect problems? Fifteen to twenty percent of adverse event reports are missing the lot numbers mandated by federal law in medical records. Inaccurate, non-existent lot numbers are found with similar frequencies. What kind of assumptions would have to be made in estimating the reduction in medical errors that may result from improved packaging? Such economic analyses would need to involve industry to document their costs, but public health or academic researchers might be better placed to explore the benefits side of the ledger. In any case, funds would have to be identified for this task.
- Wikke mentioned that Canada was moving towards national level immunization registries to keep better track of which children were vaccinated and which were late in being immunized. That is why Canada is requesting three peel-off stickers for each dose of vaccine. One for the medical record, a second for the patient's take-home vaccination booklet, and a third for a form that could be mailed to the registry.
- Bruce pointed out that he did not expect VISI to be a permanent project. Once its proposals had received formal public comment, a final version could be published as a "wish list" from the immunization community, and it would be over. It would then be up to the kind of industry working groups that Ron proposed, and the FDA, to follow through to try to implement the vision. Bruce stated that he welcomed this input from industry, and their viewpoints and ideas need to be reported in the VISI documentation.

- Ron said that the industry is not proposing to close out VISI, and that he hoped the industry positions would serve through negotiation to change the VISI proposals. He said industry is not ready to accept such detailed specifications now contained therein, such as "use RSS barcoding on the stickers" or "use *Vaccine Facts* sidebars". They are comfortable at this point with one detachable [sticky] label per dose of vaccine. Industry also wants to reduce medical errors, and the costs in suffering, and legal expenses. But these benefits have to be quantitated, as well as the costs of installing scanners by physicians.
- Jayne asked if one could assemble samples of various end-user nurses, pediatricians, family practitioners, in various types of public and private medical practices, to explore their budgets and issues around buying barcode scanners. Bruce pointed out that physicians need not spend anything on scanners; they could just use the peel-off stickers.
- Ron raised the possible effect of vaccine labeling changes on the supply of vaccine, because new label printing and applying machines could slow down the vaccine filling lines. Bruce indicated VISI neither intended not expected this to occur, as its proposals are voluntary, and would not be applicable until the technology was available to do so without any such negative effect on filling line speed.

**5. Other business**

- None

**6. Schedule of next call**

- Bruce mentioned that with the new editor on board, a goal is to have a finalized draft VISI document ready to distribute by the next conference call, and then to make it formally available afterwards for public comment.
- The next call was scheduled for Wednesday, 25 July, at 11:00 am EDT. This date was selected to leave sufficient time after a planned 13 July meeting of the industry subcommittee to develop its system specifications.